**Date application completed by the Investigator:**

**I. Research Title:**

**II. Personnel**

**A. Principal Investigator (PI)**

|  |  |  |
| --- | --- | --- |
| Name (Last, First) | Degree(s) | Net ID |
| Department | College | University Status  Student/Fellow/Resident  Faculty/Staff |
| Phone Number | UIC E-mail Address | |

**B. Faculty Sponsor** – Complete only when PI is a student, fellow, or resident

|  |  |  |
| --- | --- | --- |
| Name (Last, First) | Degree(s) | Net ID |
| Department | College | |
| Phone Number | UIC E-mail Address | |

**C. Primary Contact In Addition to PI –** Complete only if the primary contact person is different than the PI

|  |  |
| --- | --- |
| Name (Last, First) | Net ID |
| Phone Number | UIC E-mail Address |

Principal Investigator grants this personnel access to OPRS Live for this protocol

**D. List all co-investigators and key research personnel on** [Appendix P](https://go.uic.edu/irb0244) **and upload with this application packet.**

**III. Performance Sites**

**Definition of a Performance Site:**  A performance site is a location at which the research is conducted, data is gathered from subjects and/or records, and/or subjects are consented into the research. Sites are performance sites whether the research activities there are funded or not funded.

**A. Are there non-UIC performance sites?**

No

Yes – Complete [Appendix K](https://go.uic.edu/irb0254) and upload with this application packet

**IV. Research Funding**

1. **Is this research funded?**

No – *Skip to Section V.*

Yes

Pending

1. **Check all of the appropriate boxes for funding sources (including pending sources) for this research.** *If the study is supported by more than one funding source, complete and upload* [Appendix Z](https://go.uic.edu/irb0247) *for each additional funding source.*

Federal Agency Name:

Foundation Name:

State Agency Name:

Industry Sponsor Name:

The UIC OVCR assesses an administrative fee for the IRB review of all pharmaceutical industry sponsored human subjects research. Please refer to the [Protocol Processing Fee for Industry Sponsored IRB Submissions](https://go.uic.edu/irb0236) for an explanation of this policy and fee schedule. The account number to be charged must be provided below before IRB review commences.

**Account Number to be charged:**

Department of Defense – Complete [Appendix Q](https://go.uic.edu/irb0960) and upload with this application packet

Sub-contract from non-UIC agency or institution: Name:

Other - Name:

1. **Funding Identification:**

1. Institutional Proposal (IP) Number:

2. a. Name of the PI on the grant or contract received directly from the sponsor:

b. Is the PI of this grant or contract affiliated with UIC?

No – Identify the agency or institution with which the above PI is affiliated:

Explain the relationship between that agency or institution and UIC:

Yes

c. Grant, contract or sub-contract title:

d. Grant, contract or sub-contract number:

**V. Conflict of Interest (COI)**

All investigators must disclose all real, apparent, or potential Significant Financial Interest (SFI) to the IRB.For more information,see the[***Investigator Conflict of Interest Disclosure Policy for Human Subjects***](https://go.uic.edu/irb0269)***.***

**A. Disclosure**

1. At present or in the 12 months prior to this disclosure, did or does any investigator or investigator’s family members have a significant financial interest (SFI) with the research sponsor or any subcontract recipient; or have a SFI reasonably related to a product (e.g., drug, device, method, treatment, etc.) that is the subject of the research; or have any other relationships (e.g. fiduciary, even if uncompensated) that may present a potential conflict of interest with this research?

No

Yes – See Section B below.

2. Are you aware of an institutional conflict of interest with this study?

No

Yes – See Section B below.

**B. Management**

If **YES** is checked for any of these questions, complete the disclosure and management plan via START myDisclosures application (<https://myresearch.uillinois.edu/myDisclosures/>). Guidance can be found on the [COI website](https://research.uic.edu/compliance/coi/) under “Managing Conflicts”. Final IRB approval of the research cannot be provided until a management plan is in place and is approved by the IRB. For additional assistance contact the COI Office at **(312) 996-3642 / (312) 996-4070** or email [*coi@uic.edu*](mailto:coi@uic.edu).

**VI. Exemption Eligibility**

1. **Will this research involve prisoners as the PRIMARY subjects?**

No

Yes - **STOP.** *Research in which prisoners are the primary subjects is not eligible for a Claim of Exemption. Complete and upload either a* [*Health and Biological Sciences Initial Review application*](https://go.uic.edu/irb0200) *or a* [*Social and Behavioral Sciences Initial Review application*](https://go.uic.edu/irb0201) *depending on the nature of your research.*

**B. Will this research be FDA-regulated?**

No

Yes and is a taste and food quality evaluation

Yes and is **NOT** a taste and food quality evaluation - **STOP.** *FDA related research (with the exception of taste and food quality evaluation) is not eligible for a Claim of Exemption. Complete and upload a* [*Health and Biological Sciences Initial Review application*](https://go.uic.edu/irb0200)*.*

**C. Does this research meet one or more of the** [**exemption categories**](https://go.uic.edu/irb0282) **as defined by UIC?**

No - **STOP.** *This research is not eligible for a Claim of Exemption. Complete and upload either a* [*Health and Biological Sciences Initial Review application*](https://go.uic.edu/irb0200) *or a* [*Social and Behavioral Sciences Initial Review application*](https://go.uic.edu/irb0201) *depending on the nature of your research.*

Yes

**VII. Protocol Information**

**A.** Provide a rationale for the proposed research.

**B.** State the research objectives. Please include primary and secondary aims.

1. Describe in chronological order all the tasks/tests or procedures subjects, including benign behavioral interventions, and indicate the duration of subject participation. Distinguish between tasks performed solely for research and those being performed for non-research purposes.

**D.** Upload all surveys, questionnaires, interview or focus group scripts, observation plans, etc. that will be used in the research.

**VIII. Subject Population**

**A.** Number of subjects (and/or the number of cases, records, or specimens):

**B.** Indicate which populations below are the FOCUS of this research:

Adults (18 years of age and older)

Minors (17 years of age and younger)

Neonates, Fetuses, or Fetal Tissue

UIC Employees

UIC Psychology Student Subject Pool -

* *Complete* [*Appendix S*](https://go.uic.edu/irb0241) *and a debriefing document and upload with this application packet;*
* *Research involving the Psychology Student Subject Pool requires expedited review if minors are included. If minors will be excluded from the population, a scientific justification must be provided.*

UIC Management Study Pool - *Complete* [*Appendix S*](https://go.uic.edu/irb0241) *and a debriefing document and upload with this application packet*

Students - *Complete* [*Appendix S*](https://go.uic.edu/irb0241) *and upload with this application packet*

Decisionally-Impaired - *Complete* [*Appendix V*](https://go.uic.edu/irb0297) *and upload with this application packet*

Economically and/or Educationally Disadvantaged

Vulnerable to Coercion or Undue Influence

Other: specify

**IX. Recruitment**

Not Applicable, as the research does not involve an intervention or interaction - *Skip to Section X*

**A.** Describe how potential subjects will be initially identified for this research study.

**B.** Describe how, where, when, and by whom subjects will be recruited for the research.

**C.** **Check and upload all materials that will be used for recruitment.** Refer to the OPRS website for the [Investigator Guidance: Recruitment Materials](https://go.uic.edu/irb0233) for additional information.

No recruitment materials will be used

Print materials (flyer, brochure, info sheets, etc.) – Describe:

Ad (radio, TV, etc.) – Describe:

Letter – Describe:

Verbal script – Describe:

Electronic materials (e.g., website, mass mailing, email notice) – Describe:

Social Media – Specify social media outlets:

Other – Describe:

**X. Informed Consent**

Not Applicable, as the research does not involve an intervention or interaction - *Skip to Section XI*

**A.** Describe how the voluntary consent of the participants will be obtained and **attach a copy of an appropriate informed consent document** (e.g., information sheet, oral informed consent script, survey cover letter or a letter to subjects).

**B.** If you plan to allow students or trainees under the principal investigators’ supervision to recruit or obtain consent from subjects (particularly from patients, students being taught by key research personnel, employees being supervised by key research personnel, or subjects from other vulnerable groups) what safeguards will be put into place to ensure that the subjects do not feel pressured or coerced?

Not Applicable

**XI. Secondary Research**

Not Applicable - *Skip to Section XII*

“Secondary research” are studies that involve ONLY re-using data and/or biospecimens that are collected for some other “primary” or “initial” activity (e.g., other earlier research studies, a biorepository holding specimens obtained with appropriate consent, clinical care, educational records, etc.).

**A.** Describe the source of the materials (e.g., data, documents, records, biospecimens).

* *If the source was a previous or is an existing UIC IRB protocol, please provide the title, investigator name, and IRB number of the protocol.*
* *If the source of the materials is outside of UIC, please attach a letter of support from the custodian of the materials.*

**B. Upload a copy of the data collection/extraction sheets and/or a list of variables or data elements to be gathered.**

**C.** Indicate how the materials will be identified, tagged, and/or coded when they are made available to the research team:

Direct identifiers *(e.g., participant name, initials, social security number, medical record number, etc)*

Indirect identifiers *(e.g., assigned code which can be used by investigator or source to identify individual)*

No identifiers *(neither researcher nor the source can identify the individual from the information provided) – Skip to Section XII*

**D.** If the direct or indirect identifiers box is checked in item C **and** the research involves biospecimens, will all identifiers be removed and destroyed by the research team after receiving the sample?

Not applicable

No - **STOP.** Research does not qualify for exemption. *Complete and upload either a* [*Health and Biological Sciences Initial Review application*](https://go.uic.edu/irb020) *or a* [*Social and Behavioral Sciences Initial Review application*](https://go.uic.edu/irb0201) *depending on the nature of your research.*

Yes

**E.** If the direct or indirect identifiers box is checked in item C, **and** the research involves data, documents, or records, will **direct identifiers** be recorded in the research records, spreadsheets, or databases?

Not applicable

No

Yes – Are the data, documents, or records limited to identifiable health information when the use is regulated under the HIPAA Privacy Act?

No - **STOP.** Research does not qualify for exemption. *Complete and upload either a* [*Health and Biological Sciences Initial Review application*](https://go.uic.edu/irb0200) *or a* [*Social and Behavioral Sciences Initial Review application*](https://go.uic.edu/irb0201) *depending on the nature of your research.*

Yes

**F.** If the direct or indirect identifiers box is checked in item C, **and** the research involves data, documents, or records, will **indirect identifiers** be recorded in the research records, spreadsheets, or databases?

Not applicable

No

Yes – Will the research team be able to readily ascertain the subject’s identity?

No

Yes - **STOP.** Research does not qualify for exemption. *Complete and upload either a* [*Health and Biological Sciences Initial Review application*](https://go.uic.edu/irb0200) *or a* [*Social and Behavioral Sciences Initial Review application*](https://go.uic.edu/irb0201) *depending on the nature of your research.*

**G.** If the direct or indirect identifiers box is checked in item C, will the research team re-identify the subjects and/or try to contact the subjects?

Not applicable

No

Yes - **STOP.** Research does not qualify for exemption. *Complete and upload either a* [*Health and Biological Sciences Initial Review application*](https://go.uic.edu/irb0200) *or a* [*Social and Behavioral Sciences Initial Review application*](https://go.uic.edu/irb0201) *depending on the nature of your research.*

**XII. Privacy and Confidentiality**

**Data Security and Management Plan.**

1. **Indicate the identifiable elements that will be collected and/or included in the research records.**

Check all that apply

Names  Social Security Numbers**\***  Device identifiers/Serial numbers

Phone numbers  Medical record numbers  Web URLs

Street address  Health plan numbers  IP address numbers

City or state  Account numbers  Biometric identifiers1

Zip Code  Fax numbers  Vehicle ID numbers

E-mail address  License/Certificate numbers  Facial Photos/Images

Financial account information (including student ID)

All elements of dates (except year) for dates directly related to an individual; and all ages over 89 and all elements of dates (including year) indicative of such age

Date of Birth

Identifiable UIC Student Records2  University Identification Number (UIN)

Any other unique identifier - Specify:

**None of the identifiers listed above** – ***Skip to item C***

1 Biometric Identifiers are observable biological characteristics which could be used to identify an individual, e.g., fingerprints, iris/retina patterns, and facial patterns.

2 Documentation of approval from the Registrar must be submitted unless prospective signed consent is obtained from the student or guardian

**\*NOTE:** If social security numbers will be collected, explain below why they are necessary and how they will be used:

**2. Data Collection and Storage**

1. Identify all methods you will use to collect and store data:

Internet-based application/package – Specify:

REDCap [define host  CCTS/IHRP  Other (define): ]

UIC ACCCQualtrics

UIC Box

UIC Box Health Data Folder (for research involving PHI)

**\***Survey Monkey or other commercial survey service – Specify:

\*Other - A thorough description of the characteristics of the application/tool must be provided. This description should address the following elements if applicable: product/tool name, host, security measures, encryption mechanism, and how collected data is maintained and stored by the application/tool.

Non-internet based application (i.e. directly on a desktop/laptop).

Paper

Recording Media -  Photo  Video  Audio

Specify how the data will be stored and how participants will be identified in the recordings:

Subject Artifacts (such as classroom assignments, regular work products, lesson plans)

Stored specimens

Other:

**\*Note:** Any investigator who uses external survey software other than REDCap, UIC ACCC Qualtrics, or UIC Box for collecting and maintaining UIC/UI Health PHI and/or [personal data](https://ec.europa.eu/info/law/law-topic/data-protection/reform/what-personal-data_en) from individuals physically located in the [European Union Economic Area (EEA)](https://www.gov.uk/eu-eea) must provide evidence of a business associate agreement between the University and the external survey software provider. For more information, refer to the UIC HSPP policy [Research Data Security](https://go.uic.edu/irb0927). Please contact OPRS for more information regarding data collected in the EEA and the [European Union General Data Protections Regulation (EU GDPR)](https://ec.europa.eu/commission/priorities/justice-and-fundamental-rights/data-protection/2018-reform-eu-data-protection-rules_en).

1. Describe whether and how social media platforms (e.g., Facebook, Twitter, Snapchat, Amazon Mechanical Turk, etc.) will be used to collect data and/or communicate with subjects:

Not applicable

**B. Data Security**

**1.** Describe how all types of data will be secured.

a.  Indirectly with a code linked to the identity of the subject.

Describe the coding method, specify who will have access to the code/master key, indicate where the key is stored, and explain how it will be protected against unauthorized access:

b.  Directly, personal or private identifiers (identifiable elements) are maintained with the data.

Justify the inclusion of direct subject identifiers and indicate who will have access to the data:

c.  Limited Data Set [Protected Health Information (PHI) subject to the Privacy Rule that includes elements limited to city, state, ZIP Code, elements of date, and other numbers, characteristics, or codes not considered as direct identifiers]. *Requires a Data Use Agreement.*

***Please note:***

*- Items a and b require consent as per UIC policy and/or a Waiver of Authorization (if PHI is involved) from the IRB.*

*- UIC and/or outside agencies may require the use of a data use/materials transfer agreement that outlines the procedures necessary to protect identifiable or coded data or biospecimens that will be transferred or shared between agencies. You must contact the* [*Office of Research Services (ORS)*](http://research.uic.edu/lifecycle/) *at 312-996-2862 for additional information and direction.*

**2.** Indicate the method(s) used to secure each data type.

Password access

Portable devices – Specify encryption software (required):

Encryption software will be used – Specify encryption software:

Secure network server will be used – Specify secure server:

Stand alone desktop/laptop computer will be used to store data

Not connected to server/internet

An organization outside of the UIC will store the code key.

Locked file cabinet

Locked office/lab.

Locked office suite.

Locked refrigerator/freezer

Other - Specify:

**3.** Indicate when **identifiers** (including the master list, which links the study codes to the subject identifiers) will be removed or destroyed.

End of data collection

End of data analysis

Post publication/dissertation defense

Other – Specify:

**C**. **Data Sharing**

**1.**  Will the data or specimens be shared with persons **other than** UIC investigators and research staff noted on the protocol application and Appendix P?

No – *Skip to section XIII*

Yes – Specify with whom the data will be shared:

**2.** Indicate the manner in which the data will be shared:

As a de-identified dataset – *Skip to section XIII*

With direct identifiers

With indirect identifiers (i.e., coded dataset) and/or [Limited Data Set](https://privacyruleandresearch.nih.gov/dictionary.asp#l)

Identify who will have access to the code key or master list:

**3.** Specify how identifiable (coded and/or directly identifiable) data will be transferred:

Non-electronic transfer (hard copy or physical specimens) – Specify:

Transmitted over a secure network – Specify network:

Via UIC e-mail - Specify encryption:

Cloud based data sharing program (*UIC Box Health Data Folder is the only approved method of sharing PHI in this manner*)

Specify:

Other - Specify:

**XIII. Request for Waiver of HIPAA Authorization**

*Data is considered to represent PHI when an individual’s health information, including billing records, contains or is linked to one of the identifiers listed in #XII.A.1.. For example, health-related information is considered PHI if any of the following are true:*

* *The researcher obtains the information directly from a provider, billing records, health plan, health clearinghouse or employer (other than records relating solely to employment status);*
* *The records were created by any of the entities listed above and the researcher obtains the records from an intermediate source which is NOT a school record or an employer record related solely to employment status; OR*
* *The researcher obtains it directly from the study subject in the course of providing treatment to the subject.*

*Health-related information is not considered PHI if the researcher obtains it from:*

* *Student records maintained by a school;*
* *Employee records maintained by an employer related to employment status; OR*
* *The research subject directly, if the research does NOT involve treatment.*

**A*.***Indicate whether any identifiers will be recorded and/or retained with the research materials.

No – *Skip the remainder of this section.*

Yes - **Note** that thisresearch may not qualify for a Claim of Exemption as PHI cannot be retained except in very specific cases. Justify the use of PHI based on one of the following:

Research involves a Limited Data Set, as described in XII.B.1.c., above.

Secondary research use of identifiable private information that is limited to the collection and analysis of identifiable health information when its use is regulated under the HIPAA Privacy Act.

The secondary research use of identifiable private information or identifiable biospecimens is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, in accordance with 45 CFR 46.104(d)(4)(iv).

*If PHI will be retained for purposes other than those described above,* ***STOP****. Complete and upload either a* [*Health and Biological Sciences Initial Review application*](https://go.uic.edu/irb0200) *or a* [*Social and Behavioral Sciences Initial Review application*](https://go.uic.edu/irb0201)*, depending on the nature of your research.*

**B*.***Describe the plan to protect identifiers from improper use and disclosure (i.e., what measures will be used to protect identifiers during the retrieving and viewing of data from the medical records).

***In order to qualify for a Waiver of Authorization, the PHI being requested must be the minimum information necessary to accomplish the objectives of the proposed research. Note: The information obtained as part of this research (including PHI) may not be reused or disclosed to any other person or entity other than those identified on this form, except as required by law. Reuse of this information for other purposes or disclosure of the information to other individuals or entities may not occur without first seeking approval by the UIC IRB.***